

**North West - Liverpool Central Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North West - Liverpool Central Research Ethics Committee
Type of REC:	Type III
Type of Flag:	Paediatrics
Chair:	Mrs Julie Brake
Vice-Chair:	Dr Lyvonne Tume
Alternate Vice-Chair:	Mr Frank Killen
REC Manager:	Mrs Carol Ebenezer
REC Assistant:	Ms Zainab Ahmed from April 2016 Regina Caden up to March 2016
Committee Address:	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

Once again the Liverpool central Ethics Committee has had a full, varied and busy year. As always I am grateful for the commitment shown by the members of the committee who have to spend many hours reading, reviewing and reporting on a considerable amount of complex information to support researchers and participants in research.

I would like to thank you for the excellent performance towards meeting the timelines set out by the HRA, in-fact we have received many letters and emails thanking us for the speed at which we have reviewed proposals – both in the committee and as a PR, and substantial amendments, from researchers. Letters and emails of thanks have also been received with regards to the committees' reception of researchers and support and advice given during REC meetings.

Unfortunately we have lost several members over the past 12 months as Donald, Dave and Sue have left the fold, which means that our numbers have become deflated this year. Added to this is that Derek Hollingsbee is due to go this coming year. Derek is currently our only pharmacist and continues to thoroughly review nearly all CTIMPs that passed through our committee. In the last 12 months CTIMPS accounted for over 30% of all studies reviewed by us and that is a considerable amount of work so thank you all very much.

We had 0 unfavourable opinions this last year for both REC reviews and PR's even though we had some challenging studies the committee kept focused on the ethical review of the research. One again we could not achieve what we have done without the excellent work of our co-ordinator Carol and her team.

Due to our depleting numbers we have had to co-opt in on 4 occasions and I would like to thank James Burns, Stephen Edgar and Peter Owen for the help they provided.

I would like to let everyone know how much their time and effort is appreciated and for all members to look out for potential REC members of the future to join us at Liverpool Central Research Ethics Committee

North West - Liverpool Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Simon Alford	Research Manager	Lay	03/12/2013	
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Expert	01/06/2007	
Professor Murthy Burra	Consultant Anaesthetist	Expert	23/09/2011	
Mrs Hannah Chambers	Retired - Lay Member	Lay	27/09/2012	
Mr Derek Hollingsbee	Pharmacist	Expert	23/11/2006	
Professor Donald Kelly	Retired Vet	Lay Plus	23/09/2011	31/08/2015
Mr Frank Killen	Lay Member	Lay Plus	13/09/2007	
Dr Charles King	Lay Member	Lay Plus	20/11/2011	31/07/2015
Miss Karen Knowles	Biomedical Scientist	Expert	15/07/2010	
Dr Sue Palmer-Conn	Senior Lecturer	Expert	22/04/2015	16/03/2016
Mr Fotios Polydoros	Statistician	Expert	02/06/2014	
Ms Jennifer Preston	Patient and Public Involvement Manager	Lay Plus	14/09/2007	
Dr Lyvonne Tume	Senior Nursing Research Fellow Paediatric ICU	Expert	15/07/2010	
Mrs Ann Williams	Lay Member	Lay Plus	01/05/2013	

North West - Liverpool Central Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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North West - Liverpool Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr James Burns	Retired - Lay Member	Lay	01/04/2015 04/11/2115
Mr Stephen Edgar	Designer	Lay Plus	02/12/2115
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	06/01/2016

North West - Liverpool Central Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Simon Alford	none	05/01/2016
Mrs Julie Brake	Consultancy work for Boehringer Ingelheim and Lilly pharmaceuticals.	21/12/2015
Professor Murthy Burra	Council Member and Honorary Treasurer Preoperative Association. Reviewer for British Journal of Anaesthesia.	04/01/2016
Mrs Hannah Chambers	None	13/01/2016
Mr Derek Hollingsbee	Shares in Bristol Myers-Squibb.	13/01/2016
Mr Frank Killen	None	13/01/2016
Miss Karen Knowles	none	05/01/2016
Mr Fotios Polydoros	Statistician at Liverpool University CR-UK Cancer Trials Unit	22/12/2015
Ms Jennifer Preston	None	13/01/2016
Dr Lyvonne Tume	Nursing president elect (ESPNIC- European Society of Paediatric and Neonatal Intensive Care	02/03/2016
Mrs Ann Williams	Member of a NICE public health care committee. Member of food standards agency social science research committee	31/12/2015

Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	01/04/2015	9
June	03/06/2015	9
July	01/07/2015	12
September	02/09/2015	8
October	07/10/2015	11
November	04/11/2015	9
December	02/12/2015	9
January	06/01/2016	9
February	03/02/2016	10
March	02/03/2016	8

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	30/04/2015	4
May	28/05/2015	3
June	25/06/2015	4
July	15/07/2015	3
August	28/08/2015	3
September	28/09/2015	3
October	30/10/2015	4
November	26/11/2015	3
December	17/12/2015	3
March	31/03/2016	3

10 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	10/04/2015	2
April	17/04/2015	3
April	24/04/2015	2
May	01/05/2015	3
May	15/05/2015	3
May	22/05/2015	2
May	29/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
June	19/06/2015	2

June	26/06/2015	2
July	03/07/2015	2
July	08/07/2015	3
July	10/07/2015	3
July	17/07/2015	2
July	24/07/2015	2
July	31/07/2015	3
August	14/08/2015	2
August	21/08/2015	3
August	28/08/2015	3
September	11/09/2015	2
October	02/10/2015	3
October	09/10/2015	2
October	16/10/2015	2
October	23/10/2015	2
October	30/10/2015	3
November	13/11/2015	2
November	20/11/2015	2
November	20/11/2015	3
November	27/11/2015	3
December	04/12/2015	3
December	18/12/2015	3
December	24/12/2015	2
January	08/01/2016	2
January	22/01/2016	2
January	29/01/2016	2
February	05/02/2016	3
February	12/02/2016	3
February	19/02/2016	3
February	26/02/2016	2
March	04/03/2016	3
March	11/03/2016	2
March	18/03/2016	3
March	24/03/2016	3

45 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held: 01 April 2015 - 31 March 2016

None

Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Simon Alford	8
Mrs Julie Brake	9
Professor Murthy Burra	8
Mrs Hannah Chambers	8
Mr Derek Hollingsbee	7
Professor Donald Kelly	3
Mr Frank Killen	7
Dr Charles King	2
Miss Karen Knowles	7
Dr Sue Palmer-Conn	5
Mr Fotios Polydoros	7
Ms Jennifer Preston	5
Dr Lyvonne Tume	6
Mrs Ann Williams	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Simon Alford	4
Mrs Julie Brake	10
Professor Murthy Burra	2
Mrs Hannah Chambers	3
Professor Donald Kelly	4
Mr Frank Killen	1
Mr Fotios Polydoros	2
Ms Jennifer Preston	3
Dr Lyvonne Tume	1
Mrs Ann Williams	3

Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Simon Alford	1
Mrs Julie Brake	45
Mr Derek Hollingsbee	27
Mr Frank Killen	1
Dr Lyvonne Tume	36

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Simon Alford	20/05/2015	CTIMP
Mr Simon Alford	30/06/2015	Human Tissue Act Introductory
Mrs Julie Brake	09/12/2015	- National Training Day for Committee Chairs.
Professor Murthy Burra	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Hannah Chambers	24/07/2015	Personal Data in Research
Mrs Hannah Chambers	03/12/2015	Pragmatic or Point of Care Trials
Mr Derek Hollingsbee	29/09/2015	Genetic and genomic research
Mr Frank Killen	31/03/2016	Self directed learning log Raining in my heart. TV documentary on GOSH and inclusion of children in cancer trials Children and clinical research ethical issues Nuffield bioethics council report
Miss Karen Knowles	15/10/2015	Assessing the consequences of research
Mr Fotios Polydoros	20/05/2015	CTIMP
Mr Fotios Polydoros	12/06/2015	Equality and Diversity
Mr Fotios Polydoros	16/03/2016	Members national training day
Ms Jennifer Preston	31/03/2016	Self directed learning log Parents' and young people's involvement in designing a trial of ventilator weaning Lyvonne N. Tume, Jenny Preston and Bronagh Blackwood
Dr Lyvonne Tume	31/03/2016	self directed learning log An ethical framework for decision making on the post grad diploma of paediatric critical care nursing Part of a NIHR HTA research application of a trial of SDDs (drugs) in critically ill children
Mrs Ann Williams	31/03/2016	Self directed learning log Children and clinical research ethical issues Nuffield bioethics council report

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	18	31.58
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.75
Research Database (including renewals)	0	0.00
Others	38	66.67
Total Applications Reviewed	57	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	15
Number of paediatric applications reviewed	6
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	9

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	14	24.56
Unfavourable Opinion	0	0.00
Provisional Opinion	40	70.18
Provisional Opinion Pending Consultation with Referee	1	1.75
Total	57	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	40	70.18
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	14	24.56
Unfavourable Opinion	0	0.00
Provisional Opinion	1	1.75
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	57	100

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period

Total Applications Reviewed	31
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	9
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	14
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of qualitative applications reviewed	7

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	17	54.84
Favourable Opinion with Additional Conditions	7	22.58
No Opinion transfer to full committee for review	1	3.23
Provisional Opinion	6	19.35
Unfavourable Opinion	0	0.00
Total	31	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	5.7
Number of completed applications for full ethical review	57
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	0
Number of completed applications over 40 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	23
Number of completed proportionate review applications for ethical review	30
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	14
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	149
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.67%
Number of modified amendments reviewed	9
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	71
Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	66
Number of annual progress reports received	120

Number of safety reports received	34
Number of Serious Adverse Events received	0
Number of final reports received	35

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0246	Brodalumab Study in Patients with Axial Spondyloarthritis	26
15/NW/0250	Creating a web resource for patients and carers after an OCD diagnosis	26
15/NW/0254	Phase 2b/3 study in Rheumatoid Arthritis Masitinib vs Methotrexate V1	24
15/NW/0257	Scoring and Understanding of Pain: Electronic Recording - SUP:ER Study	26
15/NW/0406	TIP	29
15/NW/0427	The use of QLF-D as an oral hygiene evaluation tool in orthodontics.	23
15/NW/0461	Unlocking the functions of the left and right ventral visual cortex	39
15/NW/0465	Masitinib vs placebo in the treatment of moderate Crohn's disease-V1.0	21
15/NW/0500	POPPE Study (PK of continuous infusion of Pip/Taz in children)	24
15/NW/0537	Perinatal Access to Resources and Support (PEARS) Study	19
15/NW/0543	Tulip Study: Anifrolumab in Adults with Active SLE	20
15/NW/0545	DexEnceph 1.0	25
15/NW/0550	Metabolic phenotypes	25
15/NW/0667	Carers of stroke survivors experience of a stepped care model - V1	33
15/NW/0668	FUTURE 5	28
15/NW/0671	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	23
15/NW/0747	BI1302.5 Study-BI695502 safety and efficacy in NS Cell Lung Cancer	21
15/NW/0750	Assessing lung fibrosis with magnetic resonance imaging	27
15/NW/0758	Exome Sequencing in Endocrine disorders Version 1.0,15.08.2015	22
15/NW/0771	BEGEDINA versus 'Conventional Treatment' for treating Acute GvHD	25
15/NW/0778	Myocardial Perfusion CMR in Ischaemic Heart Disease	21
15/NW/0868	DIUR-005	21
15/NW/0876	Validation of Macimorelin as Test for Adult Growth Hormone Deficiency	22
15/NW/0902	Exercise in head and neck cancer	27
15/NW/0913	Fluids in Shock (FiSh) Feasibility Study Version 1.0	23
15/NW/0917	EMR100070-005: Avelumab vs platinum-based doublet in first line NSCLC	20
15/NW/0922	Defining and measuring Fear of Childbirth	20
15/NW/0980	An in vivo analysis of ocular surface lesions	39
16/NW/0006	SATURN: Effect of Secukinumab in the treatment of psoriatic arthritis	26
16/NW/0014	Effect of Enhanced Home Treatment on Psychiatric Inpatient Care	31
16/NW/0022	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	28
16/NW/0049	Upper Limb Function in Athletes with and without Injury (v1)	24

16/NW/0065	205212 Occluding Dentifrice Efficacy for Dentinal Hypersensitivity	19
16/NW/0068	Evaluation of Keyo in children with epilepsy	22
16/NW/0071	Study of Patidegib Gel 2%, 4%, and Vehicle in Gorlin Syndrome Patients	24
16/NW/0076	Validation study of the SystmOne GP database	25
16/NW/0137	Wearable dark-adaptometer in normal adult healthy volunteers - v.1.0	24
16/NW/0147	ODYSSEY DM - DYSLIPIDEMIA	24
16/NW/0148	Telling My Story Version 1	25
16/NW/0150	DETECT I	20

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0252	Quality and Effectiveness of Supported Tenancies (QuEST)	20
15/NW/0539	Computer vision algorithms for diabetic foot ulcer detection	19

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0247	Attachment Style Distress & Clinical Relationships in Ocular Melanoma	20
15/NW/0484	Retained Placenta Study : Part Two	19
15/NW/0544	ICARE	20
15/NW/0654	Adapting Dialectical Behaviour Therapy: What Works? v.1	21
15/NW/0661	Liverpool Musculoskeletal Biobank	21
15/NW/0679	Relatives' experiences of ECT	21
15/NW/0867	Symptom Questionnaire Study - Outcomes after OASIS	19
15/NW/0877	Perceptions of Palliative Care in Phase 1 Cancer Trials Vs 1	16
15/NW/0910	Measurement of saccades in Myasthenia Gravis	19
15/NW/0915	VOICES Project- Children's Views	19

16/NW/0010	EVIE :Slow Release Insemination Vs Standard Intrauterine Insemination	26
16/NW/0015	Exome sequencing in severe proteinuric hypertension in pregnancy	26
16/NW/0073	Metacognitive beliefs and processes in distress in MND	19
16/NW/0170	Human immune responses to flaviviruses	12

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/NW/0087	Contact Lens Device for Continuous Monitoring of Intraocular Pressure	n/a

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0390	To study the effect of Tourniquets on tissue oxygenation using NIRS	6
15/NW/0475	1) Compare platelet activation using the Advia 2120 and flow cytometry.	3
15/NW/0552	Pacemaker dependency, cardiac symptoms & QOL in dualchamber pacemakers	7

15/NW/0883	RISK-I	6
15/NW/0884	NOAC therapy: perspectives and adherence amongst AF patients	11
15/NW/0887	Information videos for use in the Paediatric Emergency department	1

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0389	Survival following acute exacerbations of COPD requiring ventilation	1
15/NW/0392	DOME: Sequential analysis of Uterine Artery Doppler Measurements	1
15/NW/0469	AAV Antibodies in UK cohort of Haemophilia A Patients	5
15/NW/0551	ITSMYasthma RCT	4
15/NW/0555	Next generation sequencing of wildtype gastrointestinal stromal tumour	1
15/NW/0605	REMOTE Study	6
15/NW/0606	Caregivers' Experiences of Psychological Interventions	7
15/NW/0607	Quantification and Piloting of ERAC (V1)	4
15/NW/0716	EVOLUTION OF THE BURDEN OF ACTIVE HEPATITIS C INFECTION IN THE UK	2
15/NW/0718	Cellular signalling in Childhood Brain Tumours and Neuroblastoma (1)	5
15/NW/0808	Oxygenation in human pulmonary microvasculature and small airways	6
15/NW/0811	RHAM - Phase 1	1
15/NW/0935	Transitional care for young people with long term conditions	2
16/NW/0243	Breath Actuated Inhaler Human Factors Placebo Study	6
16/NW/0245	Patient and Public Involvement (PPI): Feedback Cycle	11
16/NW/0247	Functional vs Anatomical Investigations of Coronary Artery Disease - 1	3
16/NW/0249	Factors influencing patient decisions for bone-anchored hearing aid V7	5

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0473	Physical activity, exercise and sport participation in trans people	4
15/NW/0479	HF-CGM study	0
15/NW/0604	Soft Touch Hard Heart	7
15/NW/0710	Questionnaire Study of Arabin Pessary Experience v.1	6
15/NW/0886	Qualitative comparison of patient views of vHIT and caloric test.	5
15/NW/0934	Biomarkers in pregnant inflammatory bowel disease patients	3
15/NW/0985	Perspectives on Accessing Type 2 Diabetes Services. Version 1.	2

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
03/06/072/A/AM04	An audit of patient centred outcomes after treatment of ocular tumours	4	29/04/2015	6
08/H1001/20/AM07	Influence of GIP on HSL, LPL and adipokines in human adipose tissue	8	27/11/2015	2
09/H1005/28/AM12	Molecular Genetics of Adverse Drug Reactions	10	27/01/2016	2
10/H1005/81/AM15	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	Ocrelizumab IB version 14 01/1	10/03/2016	5
11/H1005/10/AM16	CLL210 (CamDexRev)	12	12/06/2015	7
11/H1005/10/AM17	CLL210 (CamDexRev)	Substantial Amendment 13	07/08/2015	2
11/NW/0246/AM18	STAR: Standard vs Modified Drug Therapy in Renal Cancer	MO109353/9v8.0/1 50323	23/03/2015	2
11/NW/0327/AM03	Liverpool Primary Hepatocyte Project	2	27/10/2015	0
11/NW/0412/AM08	Comparing long term safety of LCM vs CBZ-CR in patients from SP0993	4.0	27/02/2015	25
11/NW/0412/AM09	Comparing long term safety of LCM vs CBZ-CR in patients from SP0993		14/08/2015	5
11/NW/0568/AM01	Proteomic analyses in uveal melanoma	1	02/03/2016	1
11/NW/0619/AM11	Extension to LAL-CL01 in patients with liver dysfunction due to LAL de	8.0	02/11/2015	13
11/NW/0720/AM03	The development of novel biomarkers for predicting pre-term labour	v3	23/02/2015	6
11/NW/0720/AM05	The development of novel biomarkers for predicting pre-term labour	v4	19/10/2015	7
12/NW/0045/AM21	MAJIC	16	30/07/2015	1
12/NW/0214/AM17	TAILoR: TelmisArtan and InsuLin Resistance in HIV	13	30/03/2015	3
12/NW/0214/AM18	TAILoR: TelmisArtan and InsuLin Resistance in HIV	Amendment 14, 7.0	13/05/2015	18
12/NW/0214/AM19	TAILoR: TelmisArtan and InsuLin Resistance in HIV	15	20/11/2015	9
12/NW/0263/AM11	MEK115306 A study of dabrafeniib, trametinib & combination	7	18/12/2015	18

	in melanoma			
12/NW/0350/AM03	Novel Urinary Markers of Renal Injury in Children with Cancer NUMeRICC	2	05/04/2015	4
12/NW/0350/AM04	Novel Urinary Markers of Renal Injury in Children with Cancer NUMeRICC	3.0	15/04/2015	7
12/NW/0350/AM05	Novel Urinary Markers of Renal Injury in Children with Cancer NUMeRICC	4	08/12/2015	1
12/NW/0502/AM17	Ibrutinib versus ofatumumab in relapsed/refractory CLL or SLL	Updated PIS-ICF v9.1	28/10/2015	29
12/NW/0502/AM19	Ibrutinib versus ofatumumab in relapsed/refractory CLL or SLL	IB Ed 9	06/01/2016	9
12/NW/0751/AM05	DAHANCA 21 (version 1)	6	26/04/2015	6
13/NW/0153/AM05	CIPHER	5	17/03/2015	6
13/NW/0153/AM07	CIPHER	Substantial Amendment 6	18/06/2015	1
13/NW/0280/AM12	INjection versus SplinTing in Carpal Tunnel Syndrome (INSTinCTS)	11	21/05/2015	6
13/NW/0283/AM17	Global Leaders Study V1.0	13	20/07/2015	2
13/NW/0392/AM04	Mr Bubbles	SA03	12/01/2016	2
13/NW/0494/AM10	An evaluation of a water fluoridation scheme in Cumbria-Topical Effect	Substantial Amendment 9	24/02/2015	3
13/NW/0501/AM13	Oral Azacitidine in Subjects with AML in Complete Remission	Protocol Amendment 1.1 UK; IB1	03/03/2016	12
13/NW/0567/AM05	Suitability of Nitisinone in Alkaptonuria(SONIA2)	SONIA2, Gift Voucher + IMP Rec	12/06/2015	2
13/NW/0692/AM07	CARMELINA DM CV outcome study 1218.22	IB ed13, ICF V13UK01, PGx, V02	16/03/2015	25
13/NW/0699/AM04	Phase 2 efficacy study of CC-4047+dexamethasone in renal impairment	21	04/11/2015	14
14/NW/0008/AM10	Go-colitis	7	15/05/2015	2
14/NW/0020/AM06	Standard dose versus higher and extended dose of Radium 223 in CRPC.	6	11/05/2015	2
14/NW/0020/AM10	Standard dose versus higher and extended dose of Radium 223 in CRPC.	7	20/10/2015	2
14/NW/0045/AM03	What do young people expect to happen after a referral to	3	11/03/2015	4

	CAMHS			
14/NW/0051/AM01	How physical activity affects sarcopenia in obese people with diabetes	1	30/06/2015	4
14/NW/0106/AM01	Assessing and managing pain in children who have complex needs	1	13/04/2015	0
14/NW/0123/AM02	FILTR Study - Field triage tool for ruptured aneurysms	2	22/02/2016	1
14/NW/0190/AM01	Acoustic measures in Bronchiectasis patients.	1	23/12/2014	1
14/NW/0260/AM03	Assessing the biology of the injured lung - Version 1	2	27/01/2016	2
14/NW/0277/AM03	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	3	01/04/2015	6
14/NW/0277/AM05	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	4	24/06/2015	12
14/NW/0277/AM10	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	6	19/01/2016	14
14/NW/0277/AM12	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	7	23/02/2016	5
14/NW/0279/AM02	Developing a PROM specific to patients with NF1-associated plexiforms	1	10/04/2015	21
14/NW/0279/AM03	Developing a PROM specific to patients with NF1-associated plexiforms	4	14/09/2015	15
14/NW/0279/AM04	Developing a PROM specific to patients with NF1-associated plexiforms	5	19/11/2015	0
14/NW/0279/AM05	Developing a PROM specific to patients with NF1-associated plexiforms	6	22/12/2015	1
14/NW/0279/AM07	Developing a PROM specific to patients with NF1-associated plexiforms	V7 (Amendment 5)	10/02/2016	6
14/NW/0316/AM02	Start at the beginning	2	24/03/2015	16
14/NW/0340/AM01	Dapagliflozin energy balance in T2D	LCTU Amendment 1 (a+b)	11/02/2015	4
14/NW/0340/AM03	Dapagliflozin energy balance in T2D	LCTU Amendment 3	10/06/2015	12
14/NW/0340/AM04	Dapagliflozin energy balance in T2D	4	27/10/2015	5
14/NW/0340/AM05	Dapagliflozin energy balance in T2D	5	18/02/2016	4
14/NW/0352/AM05	Pfizer TOFA A3921133-Tofa versus TNFi in Rheumatoid Arthritis	A3921133 Substantial Amendment	27/08/2015	14

14/NW/0356/AM02	How Do Male Military Veterans Cope With Psychological Difficulties? V1	2	20/05/2015	11
14/NW/1019/AM01	CPAP with or without liraglutide in sleep apnoea and diabetes	LCTU Amendments (1) + (2)	24/04/2015	6
14/NW/1019/AM04	CPAP with or without liraglutide in sleep apnoea and diabetes	4	22/12/2015	6
14/NW/1036/AM03	Study Protocol: 1408P1921	Protocol V5 (Amend. 4) and IB	11/03/2015	14
14/NW/1052/AM05	Efficacy and safety of PF-06438179 in rheumatoid arthritis	3	16/11/2015	8
14/NW/1128/AM01	Molecular profiling for lymphoma	2	05/10/2015	12
14/NW/1128/AM02	Molecular profiling for lymphoma	3	26/02/2016	1
14/NW/1147/AM02	Physical activity in those with a family history of type 2 diabetes	2	06/05/2015	6
14/NW/1199/AM01	Botulinum toxin-A versus tolterodine for idiopathic overactive bladder	1	01/06/2015	12
14/NW/1202/AM04	B7461001 - PF-06463922 in Small Cell Lung Cancer	Protocol Amendment 4	22/07/2015	8
14/NW/1202/AM05	B7461001 - PF-06463922 in Small Cell Lung Cancer	5	02/11/2015	5
14/NW/1208/AM01	Ischaemic preconditioning training in Type 2 Diabetes	1	08/09/2015	3
14/NW/1208/AM02	Ischaemic preconditioning training in Type 2 Diabetes	2	17/02/2016	0
14/NW/1219/AM10	Nerve Root Block Versus Surgery (NERVES)	Substantial Amendment 3	06/10/2015	4
14/NW/1219/AM13	Nerve Root Block Versus Surgery (NERVES)	6	17/12/2015	2
14/NW/1219/AM16	Nerve Root Block Versus Surgery (NERVES)	Substantial Amendment 8	09/02/2016	5
14/NW/1248/AM12	Tralokinumab in severe asthma	8	20/07/2015	6
14/NW/1248/AM14	Tralokinumab in severe asthma	9	17/11/2015	6
14/NW/1259/AM02	Women's Experiences of Vaginal Birth	Amendment 2	12/03/2015	7
14/NW/1259/AM03	Women's Experiences of Vaginal Birth	3	13/05/2015	3
14/NW/1259/AM04	Women's Experiences of Vaginal Birth	4	10/08/2015	2
14/NW/1259/AM05	Women's Experiences of Vaginal Birth	5	17/12/2015	5
14/NW/1300/AM01	Comparing breast, cervical and bowel cancer screening participation	1	23/11/2015	1
14/NW/1323/AM01	PIVOTAL	2	13/07/2015	7
14/NW/1323/AM02	PIVOTAL	1	21/05/2015	1
14/NW/1405/AM05	Treatment of chronic cough with PA101	2	07/05/2015	6
14/NW/1405/AM07	Treatment of chronic cough with PA101	4	10/06/2015	6

14/NW/1405/AM08	Treatment of chronic cough with PA101	Substantial Amendment 5	26/06/2015	12
14/NW/1464/AM03	Phase I Clinical testing of the Postpartum Haemorrhage Butterfly	2.4	16/01/2016	4
14/NW/1488/AM02	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	2	20/04/2015	0
14/NW/1488/AM05	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	Protocol Amendment 2	11/09/2015	17
14/NW/1488/AM06	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	5	14/03/2016	2
14/NW/1531/AM01	Comparative Testing of TVTs and Cyto-Chex BCTs	1	07/05/2015	6
14/NW/1531/AM02	Comparative Testing of TVTs and Cyto-Chex BCTs	2	26/06/2015	1
15/NW/0008/AM01	BIO BEHÄTET'S	1	22/12/2015	16
15/NW/0008/AM03	BIO BEHÄTET'S	02	15/02/2016	4
15/NW/0019/AM01	Bronchoalveolar lavage using single use bronchoscopes in HVs	1	02/06/2015	4
15/NW/0019/AM02	Bronchoalveolar lavage using single use bronchoscopes in HVs	2	27/07/2015	1
15/NW/0019/AM03	Bronchoalveolar lavage using single use bronchoscopes in HVs	3	02/09/2015	9
15/NW/0028/AM01	A Phase 3 Study to Investigate the long term safety and efficacy of ZS	Am2A	10/03/2015	9
15/NW/0028/AM02	A Phase 3 Study to Investigate the long term safety and efficacy of ZS	Am4A	11/03/2015	7
15/NW/0028/AM04	A Phase 3 Study to Investigate the long term safety and efficacy of ZS	Am5	29/04/2015	14
15/NW/0032/AM01	Imaging cerebral neuroinflammation in CVD (IN-CVD)	1	06/05/2015	5
15/NW/0032/AM03	Imaging cerebral neuroinflammation in CVD (IN-CVD)	3	26/06/2015	7
15/NW/0090/AM01	EcLiPSE Version 1.0	1.0	28/04/2015	7
15/NW/0090/AM03	EcLiPSE Version 1.0	3	16/12/2015	1
15/NW/0156/AM04	SENIOR	1	11/06/2015	2
15/NW/0156/AM05	SENIOR	2	23/07/2015	5
15/NW/0156/AM07	SENIOR	3	31/07/2015	0
15/NW/0156/AM09	SENIOR	4	01/12/2015	13
15/NW/0160/AM01	ABC08: Ph Ib Acelarin + cisplatin in advanced biliary tract cancer	Substantial Amendment 1	28/04/2015	6
15/NW/0160/AM02	ABC08: Ph Ib Acelarin + cisplatin in advanced biliary tract cancer	2	27/07/2015	4

15/NW/0247/AM02	Attachment Style Distress & Clinical Relationships in Ocular Melanoma	2	23/11/2015	2
15/NW/0406/AM01	TIP	1.0	03/09/2015	15
15/NW/0406/AM02	TIP	2.0	28/10/2015	14
15/NW/0406/AM03	TIP	Three	07/03/2016	5
15/NW/0427/AM01	The use of QLF-D as an oral hygiene evaluation tool in orthodontics.	1	15/10/2015	15
15/NW/0484/AM01	Retained Placenta Study : Part Two	1	07/10/2015	6
15/NW/0484/AM02	Retained Placenta Study : Part Two	2	01/03/2016	0
15/NW/0500/AM01	POPET Study (PK of continuous infusion of Pip/Taz in children)	4.0	30/10/2015	15
15/NW/0537/AM01	Perinatal Access to Resources and Support (PEARS) Study	1	02/02/2016	1
15/NW/0537/AM02	Perinatal Access to Resources and Support (PEARS) Study	2	17/02/2016	0
15/NW/0543/AM02	Tulip Study: Anifrolumab in Adults with Active SLE	1	30/12/2015	7
15/NW/0545/AM02	DexEnceph 1.0	1	27/10/2015	2
15/NW/0551/AM01	ITSMYasthma RCT	1	17/08/2015	6
15/NW/0551/AM02	ITSMYasthma RCT	2	10/09/2015	15
15/NW/0551/AM04	ITSMYasthma RCT	3	08/02/2016	2
15/NW/0607/AM01	Quantification and Piloting of ERAC (V1)	1	28/01/2016	1
15/NW/0671/AM02	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	2.1	14/10/2015	1
15/NW/0671/AM07	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	4	22/02/2016	7
15/NW/0750/AM01	Assessing lung fibrosis with magnetic resonance imaging	1	05/02/2016	2
15/NW/0867/AM01	Symptom Questionnaire Study - Outcomes after OASIS	1	01/01/2016	1
15/NW/0868/AM01	DIUR-005	1	19/02/2016	5
15/NW/0884/AM01	NOAC therapy: perspectives and adherence amongst AF patients	1	29/01/2016	4
15/NW/0922/AM01	Defining and measuring Fear of Childbirth	1	15/02/2016	2
15/NW/0935/AM01	Transitional care for young people with long term conditions	1	09/02/2016	1
16/NW/0022/AM02	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	002	23/02/2016	14
16/NW/0071/AM01	Study of Patidegib Gel 2%, 4%, and Vehicle in Gorlin Syndrome Patients	Protocol Amendment version 3.0	07/03/2016	8
97/141/AM36	The Liverpool Lung Project	43	17/03/2015	10
97/141/AM37	The Liverpool Lung Project	45	14/07/2015	7
97/141/AM38	The Liverpool Lung Project	46	16/12/2015	20

EC.47.01/AM04	Molecular techniques for the diagnosis & monitoring of oral dysplasia	8	23/10/2015	7
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Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1005/81/AM13	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	6	26/03/2015	25
12/NW/0723/AM15	GN28525- EXTENSION STUDY MILD TO MODERATE ALZHEIMER'S DISEASE	1	02/11/2015	14
13/NW/0056/AM01	Patient Presentation Delay in Oral Cancer - Version 1	2	09/07/2015	2
13/NW/0501/AM06	Oral Azacitidine in Subjects with AML in Complete Remission	0,1	13/10/2015	14
14/NW/0045/AM04	What do young people expect to happen after a referral to CAMHS	5	01/07/2015	7
14/NW/0186/AM07	ESTEEM Study to collect information on DMF utilization and safety	4	07/08/2015	26
14/NW/1019/AM03	CPAP with or without liraglutide in sleep apnoea and diabetes	3	26/10/2015	7
14/NW/1248/AM09	Tralokinumab in severe asthma	7	31/03/2015	7

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1005/81/AM13/1	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	E Modification of Amendment da	06/02/2015	5
12/NW/0723/AM15/1	GN28525- EXTENSION STUDY MILD TO MODERATE ALZHEIMER'S DISEASE		10/02/2016	2
13/NW/0056/AM01/1	Patient Presentation Delay in Oral Cancer - Version 1	Third Amendment	27/07/2015	1
14/NW/0045/AM04/1	What do young people expect to happen after a referral to CAMHS	5 modified	24/07/2015	5
	ESTEEM Study to collect information on DMF utilization and	5	24/11/2015	7

14/NW/0186/AM07/1	safety			
14/NW/1019/AM03/2	CPAP with or without liraglutide in sleep apnoea and diabetes	3 Modified	05/01/2016	8
14/NW/1248/AM09/2	Tralokinumab in severe asthma	Modified Amendment 2	31/03.2015	1

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/NW/0501/AM06/1	Oral Azacitidine in Subjects with AML in Complete Remission	3	22/12/2015	1
14/NW/1019/AM03/1	CPAP with or without liraglutide in sleep apnoea and diabetes	3	22/12/2015	1

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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